IRBNet User's Manual

University of Denver

Institutional Review Board (IRB)

Human Subjects Protection Program

Office of Research Compliance

UNIVERSITY of DENVER

RESEARCH & SPONSORED PROGRAMS

Version date: 7/6/15

INTRODUCTION

The DU IRB is responsible for ensuring that any research study under its jurisdiction is in compliance with federal, state, and institutional regulations. All submissions must be submitted electronically to the DU IRB through IRBNet. IRBNet is a hosted service that supports electronic, on-line submissions. No hard copies will be accepted. IRBNet can be accessed at the following web address:

The Web Address:

www.irbnet.org

The purpose of this document is to provide guidance for submitting to the DU IRB via IRBNet. Step-by-step instructions will be given for each type of submission.

NEED ADDITIONAL ASSISTANCE?

If you have any questions and require additional assistance navigating through IRBNet program, please contact the DU IRB/Office of Research Compliance at 303-871-4050.

Thank You!

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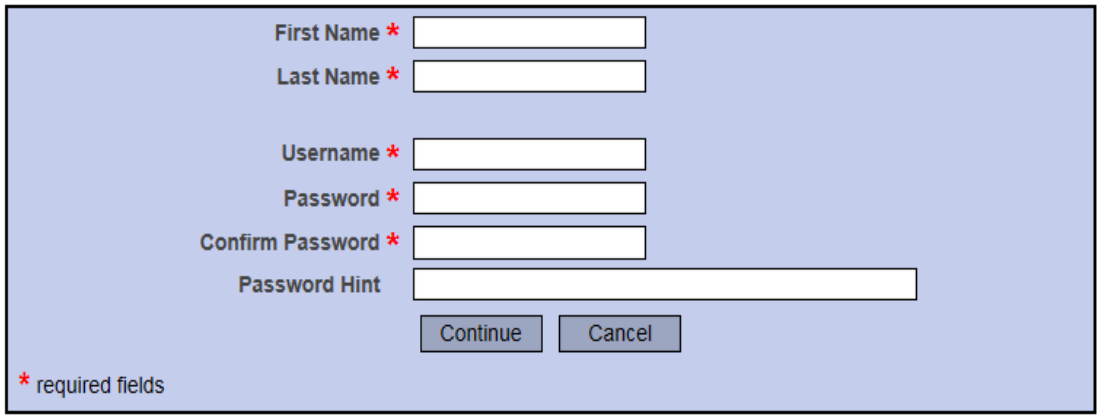
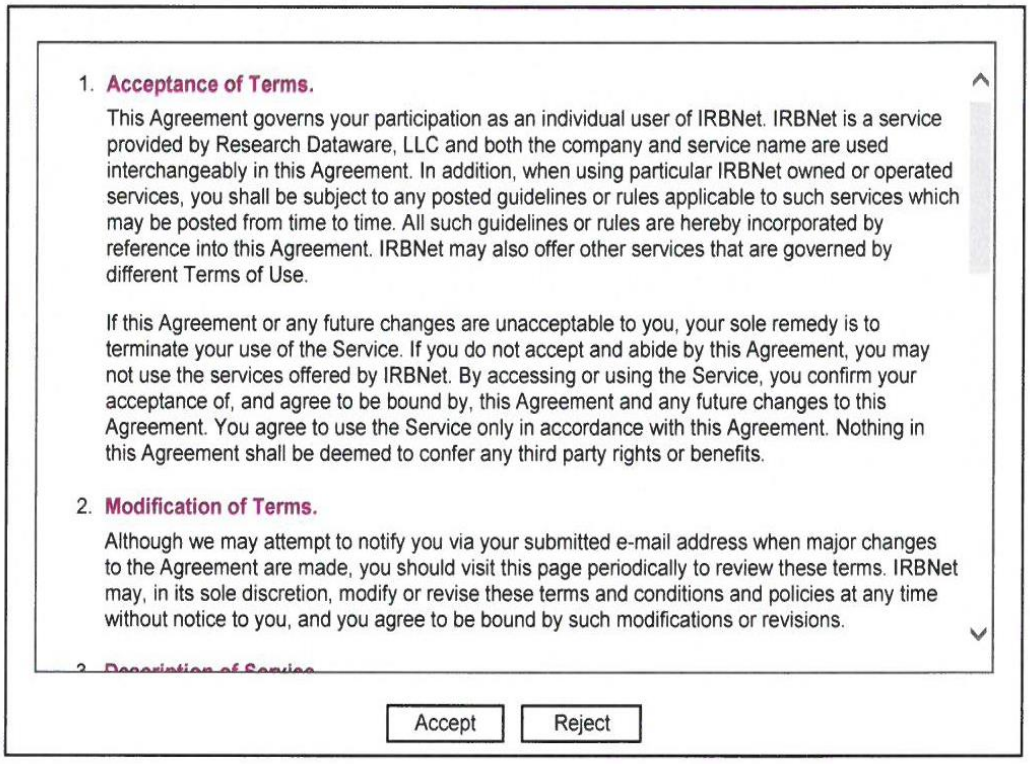
I. INSTRUCTIONS FOR REGISTERING WITH IRBNET

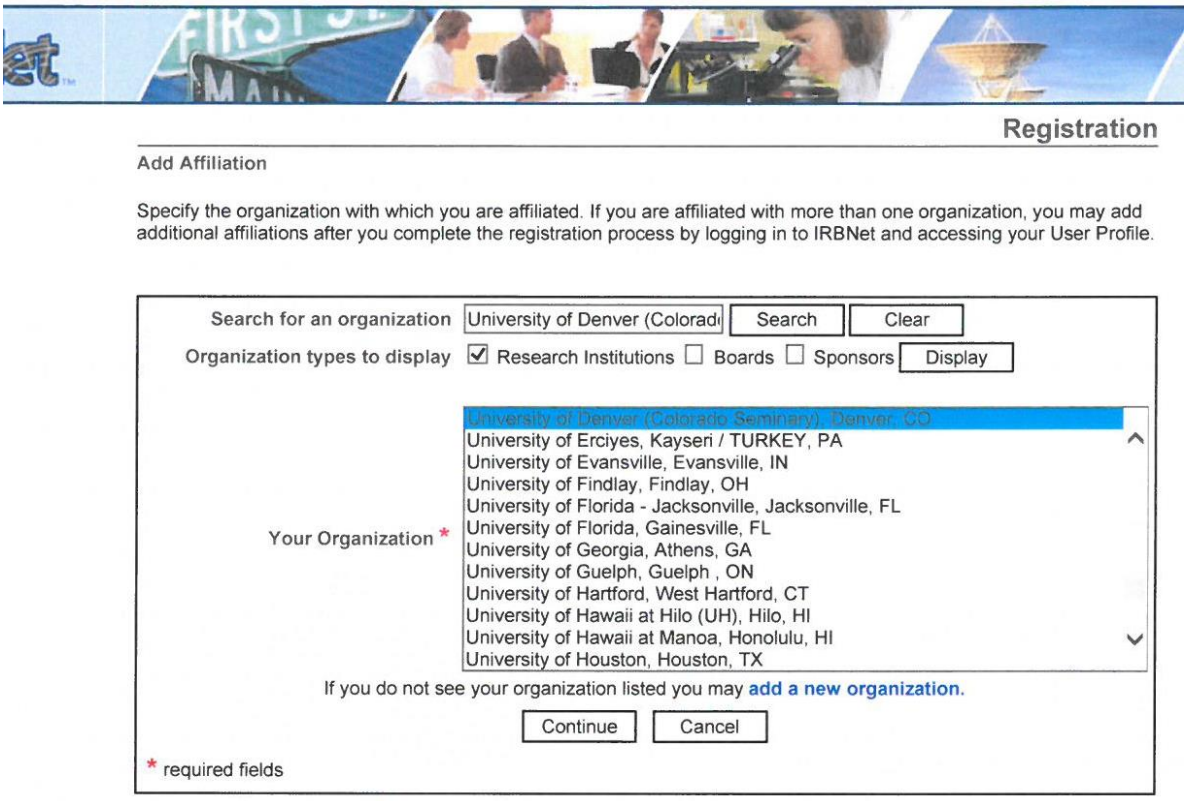
1. Go to http://www.irbnet.org
2. Click on the 'New User Registration' link in the upper right-hand corner of the screen
3. Create your username and password. Fill out the required information. Your password must contain 8 characters. Click 'Continue'



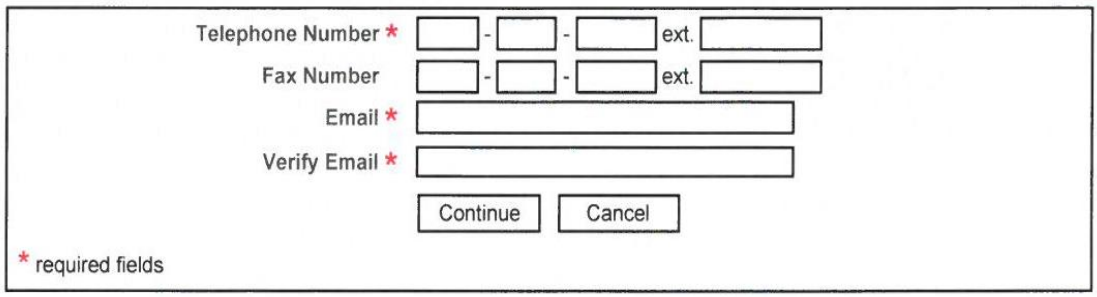
4. Read and Accept the Individual User Terms of Use


1. Acceptance of Terms.
This Agreement governs your participation as an individual user of IRBNet. IRBNet is a service provided by Research Dataware, LLC and both the company and service name are used interchangeably in this Agreement. In addition, when using particular IRBNet owned or operated services, you shall be subject to any posted guidelines or rules applicable to such services which may be posted from time to time. All such guidelines or rules are hereby incorporated by reference into this Agreement. IRBNet may also offer other services that are governed by different Terms of Use.
If this Agreement or any future changes are unacceptable to you, your sole remedy is to terminate your use of the Service. If you do not accept and abide by this Agreement, you may not use the services offered by IRBNet. By accessing or using the Service, you confirm your acceptance of, and agree to be bound by, this Agreement and any future changes to this Agreement. You agree to use the Service only in accordance with this Agreement. Nothing in this Agreement shall be deemed to confer any third party rights or benefits.
2. Modification of Terms.
Although we may attempt to notify you via your submitted e-mail address when major changes to the Agreement are made, you should visit this page periodically to review these terms. IRBNet may, in its sole discretion, modify or revise these terms and conditions and policies at any time without notice to you, and you agree to be bound by such modifications or revisions.
Accept
Reject

5. To add your affiliation, type the word, 'University of Denver (Colorado Seminary), Denver, CO' into the search box. Click 'Display'. Select 'University of Denver (Colorado Seminary), Denver, CO' from the organization box. Click 'Continue'


Registration
Add Affiliation
Specify the organization with which you are affiliated. If you are affiliated with more than one organization, you may add additional affiliations after you complete the registration process by logging in to IRBNet and accessing your User Profile.
Search for an organization
University of Denver (Colorad
Search
Clear
Organization types to display
Research Institutions
Boards
Sponsors
Display
Your Organization *
University of Denver (Colorado Seminary), Denver, CO
University of Erciyes, Kayseri / TURKEY, PA
University of Evansville, Evansville, IN
University of Findlay, Findlay, OH
University of Florida - Jacksonville, Jacksonville, FL
University of Florida, Gainesville, FL
University of Georgia, Athens, GA
University of Guelph, Guelph , ON
University of Hartford, West Hartford, CT
University of Hawaii at Hilo (UH), Hilo, HI
University of Hawaii at Manoa, Honolulu, HI
University of Houston, Houston, TX
If you do not see your organization listed you may add a new organization.
Continue
Cancel
* required fields

6. Enter your contact information. Enter the email address you will use to receive communications through the IRBNet system regarding all notifications of IRB decisions, communications from the IRB Office and/or your research. Click 'Continue'



7. Review the information you provided and edit as necessary. When you are satisfied, click 'Register'

IMPORTANT: An email will be sent to the email address you provided in Step 6, with 'IRBNet Activation Required' in the subject line. If you do not receive the confirmation in a short period of time then check your

junk folder to see if it is there. You will need to click on the link provided in this registration email in order to activate your account. Clicking on the link will take you automatically to the IRBNet homepage.

If you have problems activating your account or have forgotten your password, please click on the “Forgot your Password?” text in the upper right corner of the IRBNet home page.

IRBNet
Innovative Solutions for
Compliance and Research Management
Login:
Username
Password
Login
New User Registration
Forgot Your Password?
Home
The IRBNet Difference
Demo
Contact Us
FAQ
Comprehensive Solutions
The Industry's Most Complete Solution
IRBNet's unmatched suite of electronic solutions drives compliance and productivity for your Administrators, Committee Members, Researchers and Sponsors. These powerful research design, management and oversight tools support your IRB, IACUC, IBC, COI and other Boards with a unified solution.
Flexible, Intuitive and Easy to Use
Your own forms. Your own processes. Your own standards. Powerful reporting and performance metrics. The data you need. From electronic submissions to form wizards, to agendas, minutes, and more. Our easy to use, web-based tools are rapidly launched and backed by our best practices expertise and the industry's leading support team.
Test Drive IRBNet
See for yourself...
Demo
Satisfied Members
"Our first electronic meeting went so smoothly! It was over so fast the members didn't know what to do. They just sat there for a few minutes in disbelief."
- Bruce Day
Director, Office of Research Integrity
Marshall University

III. INSTRUCTIONS FOR INITIAL SUBMISSIONS – CREATE A NEW PROJECT

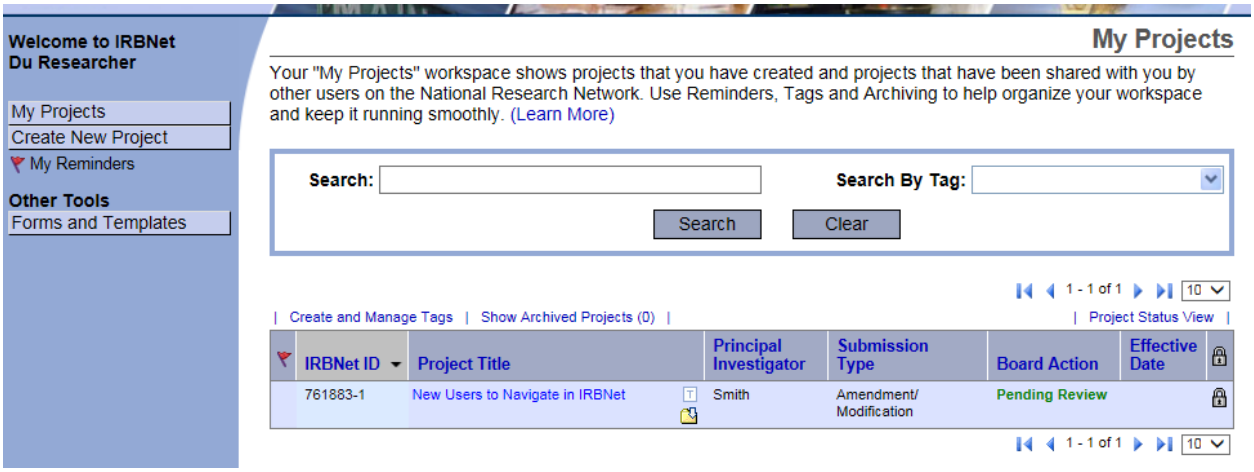
To submit a study for review, you must first **CREATE A NEW PROJECT** (Study) to hold your documents. Any type of document can be uploaded, but your study MUST include all the required forms for a complete package before any action can be taken on behalf of the board. A good place to start is 'Checklist – New Submissions' which includes a list of the required forms for a New Study. This, and other checklists, can be found under 'Other Tools' (Forms and Templates) on the left side of your screen.

Please note: If you are submitting on behalf of the Principal Investigator (PI), the PI must be registered in IRBNet so that he/she can sign your package later in the submission process.

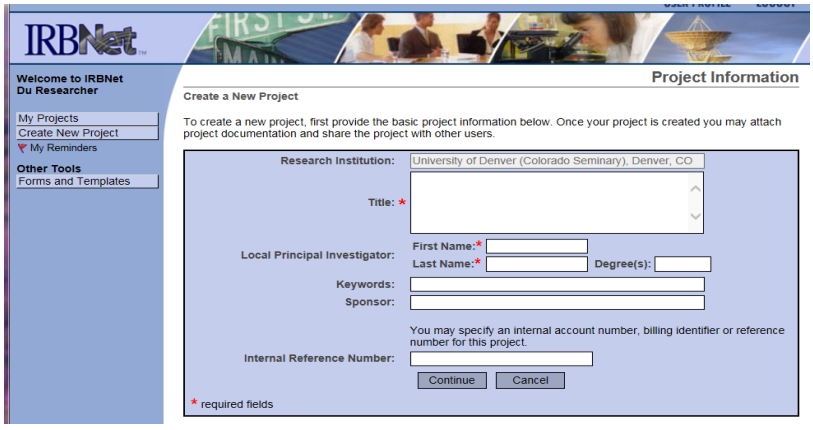
STUDENTS: If you are serving as the Principal Investigator (PI) on this new project, your Faculty Advisor must be registered in IRBNet so that he/she can review and sign your package during in the submission process.

Step 1: Log In to www.irbnet.org using you username and password (for First Time Users, you must Register with IRBNet; please see INSTRUCTIONS FOR REGISTERING WITH IRBNET / page 3)

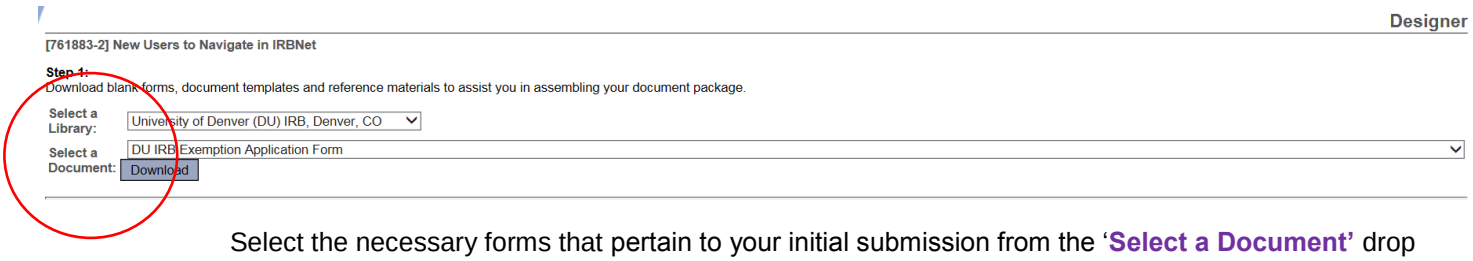
Step 2: The default page will be **MY PROJECTS**, where you will have access to all of your existing studies as well as the ability to create new studies. Click **CREATE NEW PROJECT** (on the left side of your screen).



Fill in the relevant information about your project (title, PI name), click 'Continue'

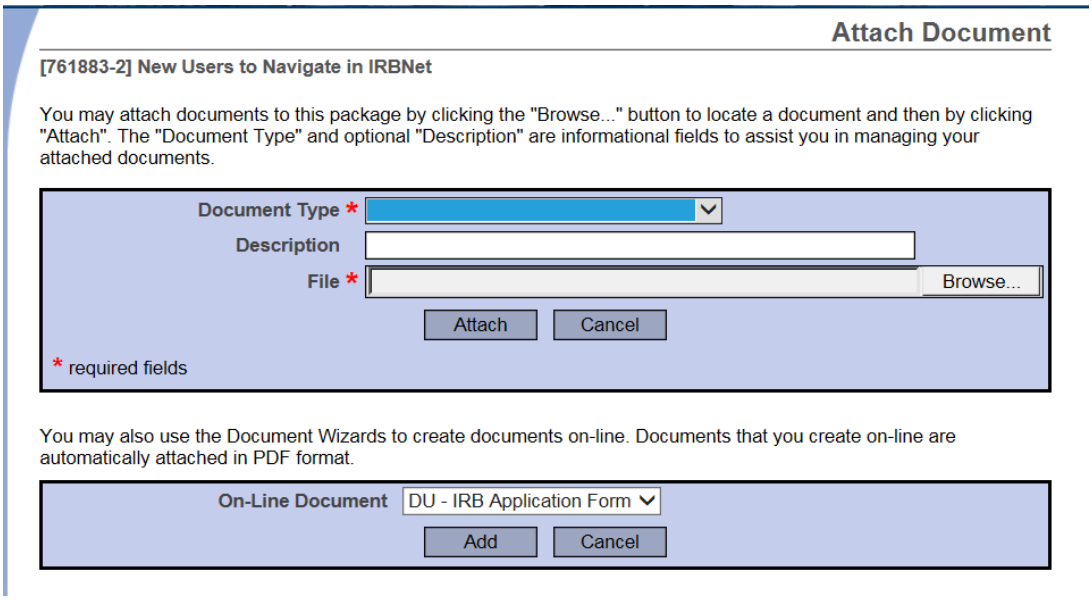


Step 3: You will now be on the **DESIGNER** page where you will download forms, templates, and reference materials to assemble a new study. Select 'University of Denver (DU) IRB, Denver, CO – Documents for Researchers' from the 'Select a Library' drop-down menu.


Designer
[761883-2] New Users to Navigate in IRBNet
Step 1:
Download blank forms, document templates and reference materials to assist you in assembling your document package.
Select a Library:
University of Denver (DU) IRB, Denver, CO
Select a Document:
DU IRB Exemption Application Form
Download

Select the necessary forms that pertain to your initial submission from the '**Select a Document'** drop down menu. Save these documents to your computer in a place where you can find them again (i.e. desktop, My Documents, etc.). Click the 'Browse' button and find the completed document on your hard drive. Once you find the document, click the 'Attach' button to upload the document. Assemble your document package through clicking on '**Add New Document'** until all documents have been added, and use the checklist as a reference guide.

Label your document appropriately using the drop down list on the '**Attach Document**' screen (i.e. Application Form, Consent Form, Protocol, Letter, etc.).


Attach Document
[761883-2] New Users to Navigate in IRBNet
You may attach documents to this package by clicking the "Browse..." button to locate a document and then by clicking "Attach". The "Document Type" and optional "Description" are informational fields to assist you in managing your attached documents.
Document Type *
Description
File *
Browse...
Attach
Cancel
* required fields
You may also use the Document Wizards to create documents on-line. Documents that you create on-line are automatically attached in PDF format.
On-Line Document
DU - IRB Application Form
Add
Cancel

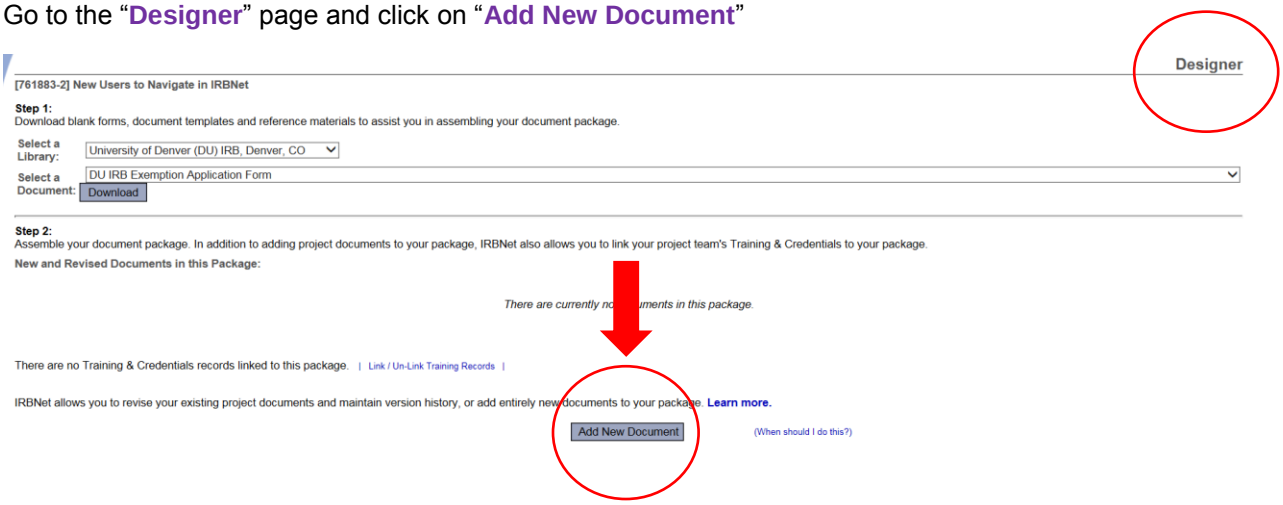
Once you have attached a document to your study package, the Study Designer page will now list your documents.

PLEASE NOTE: THE ON-LINE DOCUMENT (DU-IRB Application Form) MUST ALSO BE COMPLETED. Please refer to the instructions for completing this application on the following page.

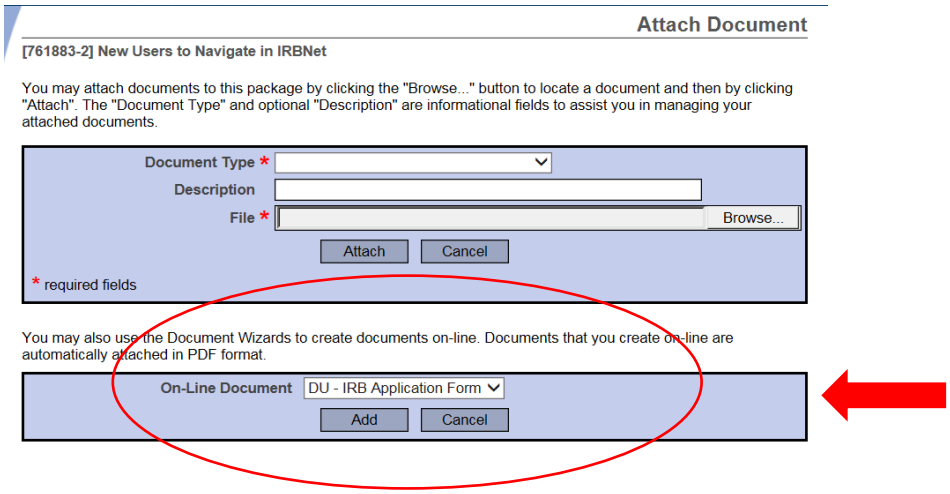
ON-LINE DOCUMENT
(DU IRB Application)

Please Note: The On-line Document provides detailed information about your study that may not be listed in the protocol or the informed consent. **The On-line Document MUST be completed for ALL initial submissions.**

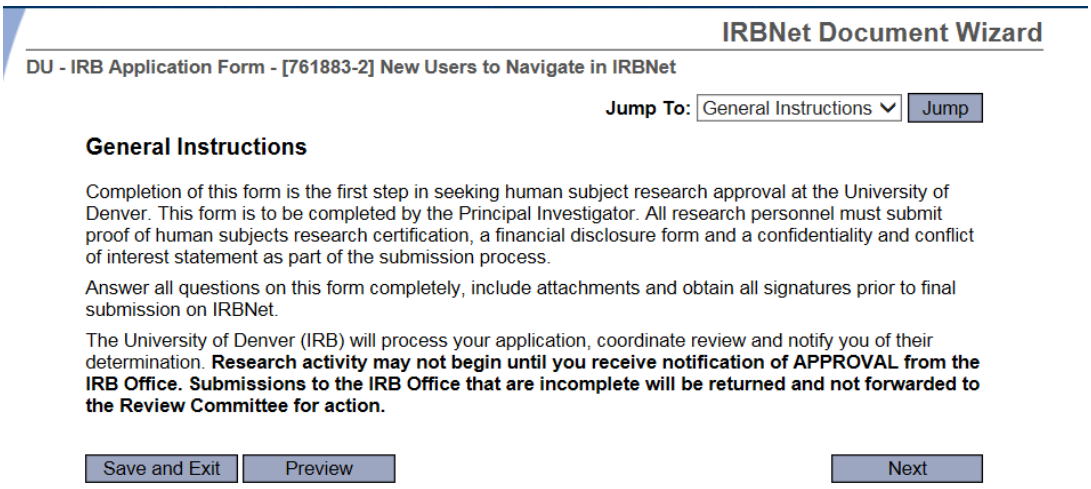
Go to the "**Designer**" page and click on "**Add New Document**"


Designer
[761883-2] New Users to Navigate in IRBNet
Step 1:
Download blank forms, document templates and reference materials to assist you in assembling your document package.
Select a Library:
University of Denver (DU) IRB, Denver, CO
Select a Document:
DU IRB Exemption Application Form
Download
Step 2:
Assemble your document package. In addition to adding project documents to your package, IRBNet also allows you to link your project team's Training & Credentials to your package.
New and Revised Documents in this Package:
There are currently no documents in this package.
There are no Training & Credentials records linked to this package.
Link / Un-Link Training Records
IRBNet allows you to revise your existing project documents and maintain version history, or add entirely new documents to your package.
Learn more.
Add New Document
(When should I do this?)

Go to the '**On-Line Document**' (DU IRB Application) at the bottom of the **DESIGNER** page and click 'ADD'.


Attach Document
[761883-2] New Users to Navigate in IRBNet
You may attach documents to this package by clicking the "Browse..." button to locate a document and then by clicking "Attach". The "Document Type" and optional "Description" are informational fields to assist you in managing your attached documents.
Document Type *
Description
File *
Browse...
Attach
Cancel
* required fields
You may also use the Document Wizards to create documents on-line. Documents that you create on-line are automatically attached in PDF format.
On-Line Document
DU - IRB Application Form
Add
Cancel

Once you click "ADD", you will automatically be directed to the General Instructions for completing the DU – IRB Application Form. All fields with a red asterisk * are required to be completed. The online application does not allow the user to continue until that field has been completed.

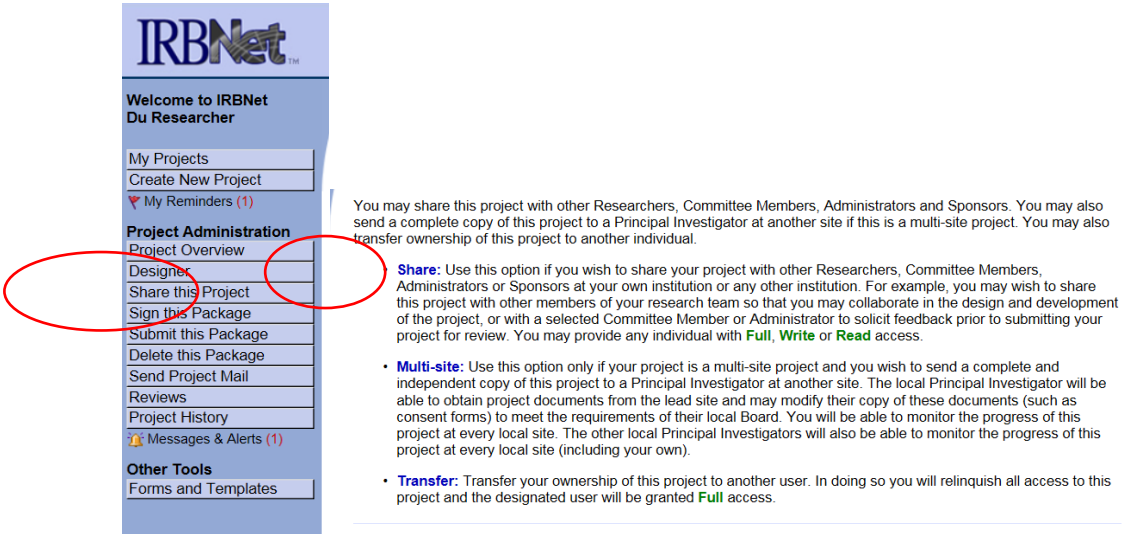

IRBNet Document Wizard
DU - IRB Application Form - [761883-2] New Users to Navigate in IRBNet
Jump To: General Instructions
Jump
General Instructions
Completion of this form is the first step in seeking human subject research approval at the University of Denver. This form is to be completed by the Principal Investigator. All research personnel must submit proof of human subjects research certification, a financial disclosure form and a confidentiality and conflict of interest statement as part of the submission process.
Answer all questions on this form completely, include attachments and obtain all signatures prior to final submission on IRBNet.
The University of Denver (IRB) will process your application, coordinate review and notify you of their determination. Research activity may not begin until you receive notification of APPROVAL from the IRB Office. Submissions to the IRB Office that are incomplete will be returned and not forwarded to the Review Committee for action.
Save and Exit
Preview
Next

Complete this form, then click 'SAVE AND EXIT'.

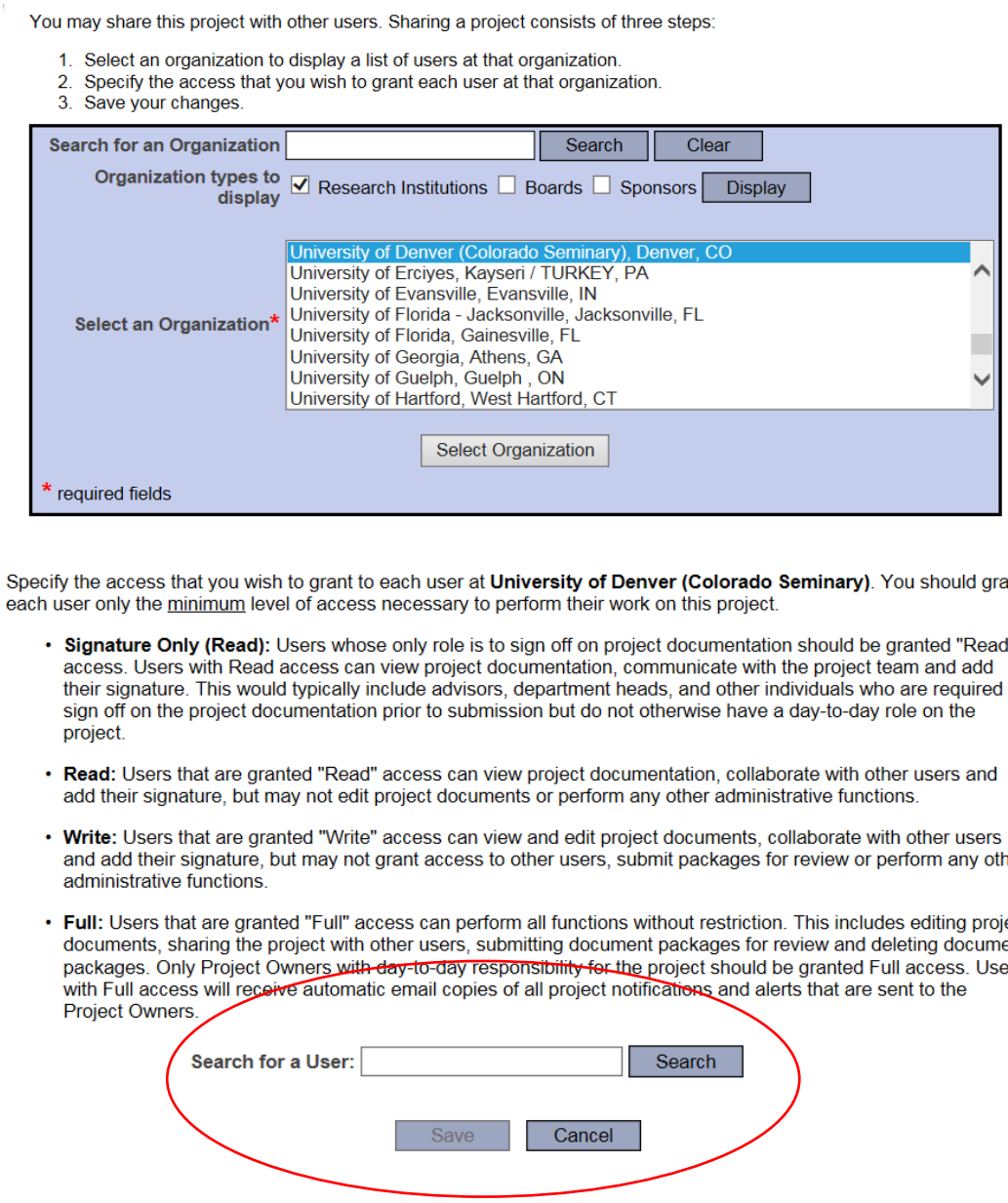
You do not need to complete the entire online form in one sitting; you can 'save and exit', and then go back and update the document by clicking the pencil icon next to the document listed in the designer. When you have completed the DU IRB Application, click 'Preview' to see what the completed form looks like, and confirm that all the information provided is accurate.

PLEASE NOTE: All other IRB forms are to be completed, saved to your hard drive, and attached to the submission package.

Step 4: SHARE THIS PROJECT with your research team, and if a student investigator, with your Faculty Advisor. Click the '**Share this Project**' button on the left side of your screen; click the blue '**Share**' link to grant access to this project.


IRBNet
Welcome to IRBNet
Du Researcher
My Projects
Create New Project
My Reminders (1)
Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Messages & Alerts (1)
Other Tools
Forms and Templates
You may share this project with other Researchers, Committee Members, Administrators and Sponsors. You may also send a complete copy of this project to a Principal Investigator at another site if this is a multi-site project. You may also transfer ownership of this project to another individual.
Share: Use this option if you wish to share your project with other Researchers, Committee Members, Administrators or Sponsors at your own institution or any other institution. For example, you may wish to share this project with other members of your research team so that you may collaborate in the design and development of the project, or with a selected Committee Member or Administrator to solicit feedback prior to submitting your project for review. You may provide any individual with Full, Write or Read access.
Multi-site: Use this option only if your project is a multi-site project and you wish to send a complete and independent copy of this project to a Principal Investigator at another site. The local Principal Investigator will be able to obtain project documents from the lead site and may modify their copy of these documents (such as consent forms) to meet the requirements of their local Board. You will be able to monitor the progress of this project at every local site. The other local Principal Investigators will also be able to monitor the progress of this project at every local site (including your own).
Transfer: Transfer your ownership of this project to another user. In doing so you will relinquish all access to this project and the designated user will be granted Full access.

Select **"University of Denver (Colorado Seminary) , Denver, CO'** from the organization box; click 'Select Organization' and search for registered users with whom you'd like to share this project (i.e. Co-investigators, Faculty Advisor, Research Assistant, etc.) Grant each user a level of ACCESS:

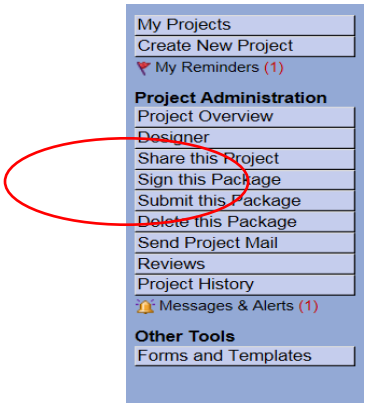

You may share this project with other users. Sharing a project consists of three steps:
1. Select an organization to display a list of users at that organization.
2. Specify the access that you wish to grant each user at that organization.
3. Save your changes.
Search for an Organization
Search
Clear
Organization types to display
Research Institutions
Boards
Sponsors
Display
Select an Organization*
University of Denver (Colorado Seminary), Denver, CO
University of Erciyes, Kayseri / TURKEY, PA
University of Evansville, Evansville, IN
University of Florida - Jacksonville, Jacksonville, FL
University of Florida, Gainesville, FL
University of Georgia, Athens, GA
University of Guelph, Guelph , ON
University of Hartford, West Hartford, CT
Select Organization
* required fields
Specify the access that you wish to grant to each user at University of Denver (Colorado Seminary). You should grant each user only the minimum level of access necessary to perform their work on this project.
Signature Only (Read): Users whose only role is to sign off on project documentation should be granted "Read" access. Users with Read access can view project documentation, communicate with the project team and add their signature. This would typically include advisors, department heads, and other individuals who are required to sign off on the project documentation prior to submission but do not otherwise have a day-to-day role on the project.
Read: Users that are granted "Read" access can view project documentation, collaborate with other users and add their signature, but may not edit project documents or perform any other administrative functions.
Write: Users that are granted "Write" access can view and edit project documents, collaborate with other users and add their signature, but may not grant access to other users, submit packages for review or perform any other administrative functions.
Full: Users that are granted "Full" access can perform all functions without restriction. This includes editing project documents, sharing the project with other users, submitting document packages for review and deleting document packages. Only Project Owners with day-to-day responsibility for the project should be granted Full access. Users with Full access will receive automatic email copies of all project notifications and alerts that are sent to the Project Owners.
Search for a User:
Search
Save
Cancel

To 'Share' your research with someone, they must be registered with IRBNet.org

Selected users will be notified automatically via email that the project has been shared with them, and you may enter comments to be included within the email.

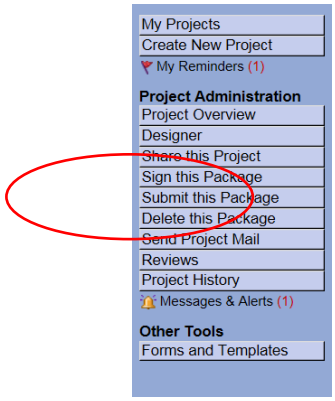
Step 5: When all the necessary documents are uploaded to the package, the Principal Investigator must sign the package electronically. If you are completing this package on behalf of the PI, send an email to the PI using the '**Send Project Mail**' function and request that the PI sign the package**.** **If you are a student, send an email to your Faculty Advisor using the 'Send Project Mail' function and request that the Faculty Advisor sign the package.**

Step 6: Click on **SIGN THIS PACKAGE**. The Principal Investigator MUST sign the package before it is submitted. Select your appropriate role from the dropdown box and click 'Sign'.



If a submission is submitted without the PI signature, or Faculty Advisor's signature, the submission will not be accepted for review.

Step 7: Once the PI has signed the package, click **SUBMIT THIS PACKAGE**. Select 'University of Denver (DU), Denver, CO' in the "Search for Organization" drop down menu (This will be your default location and should be highlighted already).



Then click the 'Continue' button. In the Submission Type drop-down menu, select '**New Project**' and click 'Submit'.

Once you hit the 'Submit' button, you will be given a confirmation showing the time your submission occurred.

Step 8: To review what has been sent, click **PROJECT OVERVIEW**. The submission will be under 'Pending Review' status until a decision by the board has been made. Once a decision letter is formulated, an email will be sent to everyone who has full access and the letter and any supporting documents can be printed.

*NOTE: Keep in mind that once you click 'Submit' your study is locked and no other changes can be made to this package. Take the time to be sure all documents are attached and in the final version **prior to submitting**. Any incomplete submissions will not be reviewed by the IRB and will be returned for corrections. If you need to make any changes after the package has been submitted and locked, please contact the IRB Office to request to have the package unlocked.*

INSTRUCTIONS FOR SUBMITTING A CONTINUING REVIEW

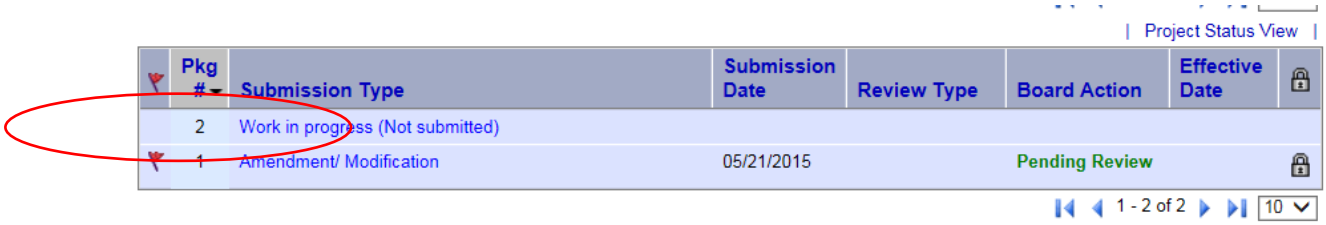
The submission of a continuing review of an open study requires the creation of a subsequent package in a project.

Step 1: Login to IRBNet: www.irbnet.org. This will take you to the **MY PROJECTS** page. This is where all of the studies that you have access to will be housed.

Step 2: Click on the Title of the project that you would like to continue/renew (click on the exact IRBNet project referenced in the e-mail you received reminding you to renew your study). Then click on the **PROJECT HISTORY**

Step 3: Click on **CREATE NEW PACKAGE**

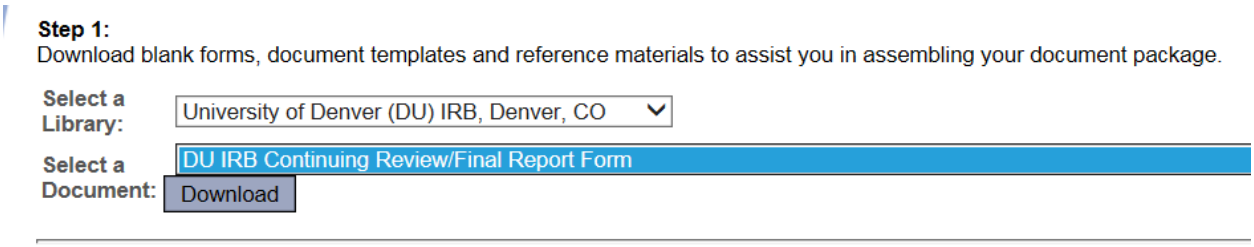
Step 4: A **NEW DOCUMENT PACKAGE** will appear as a 'Work in Progress". Click on the New Document Package title and you will be brought to the DESIGNER screen where you can add your documents for this package.



Step 5: You will be on the **DESIGNER** page.

This is where you can access the library of forms as well as any documents from previous packages you have submitted.

From the DU IRB Library (Step 1: - top of screen), Select and download both 'Checklist – Continuing Reviews' and 'Continuing Review Application' form the **'Select A Document**' drop down box. From here, choose File>Save As to save the document to your computer, complete the Continuing Review/Progress Report Application Form, save it to your hard drive, and use the checklist as a reference.


Step 1:
Download blank forms, document templates and reference materials to assist you in assembling your document package.
Select a Library:
University of Denver (DU) IRB, Denver, CO
Select a Document:
DU IRB Continuing Review/Final Report Form
Download

View the On-Line Document (DU IRB Application) and verify that the data accurately reflects the current status of your study. If changes have occurred to your study that have not previously been reviewed and approved by the IRB, then an amendment/modification will be required.

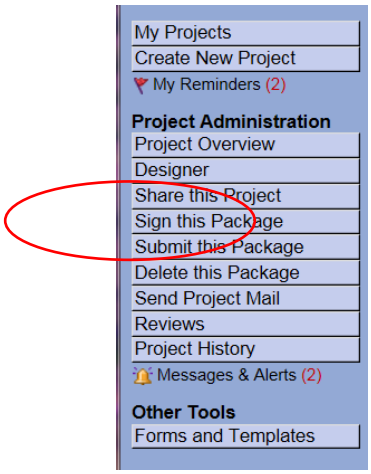
Attach supporting documents for your continuing review package by clicking on the 'Add New Document' button and browsing your computer:

In the Document Type drop-down box, pick the best match for the document you are uploading. If it is the application, choose the '**Continuing Review/Progress Report**' choice. If the type of document you are submitting is not in the list then choose "Other" and enter the type of document in the Description field.

Click the 'Browse' button and find the document on your hard drive. Once you find the document click the 'Attach' button to upload the document.

Step 6: When all required continuing review documents are uploaded, the PI needs to sign the package electronically. If you are a student, send a Project Mail to your Faculty Advisor requesting them to sign the package.

Step 7: To sign a package, click **SIGN THIS PACKAGE**. The Principal Investigator, or if applicable, the Faculty Advisor, MUST sign the package before it is submitted. Select your appropriate role from the dropdown box and click 'Sign'.



If a submission is submitted without a PI signature, or if applicable, a Faculty Advisor signature, the submission will not be accepted for review.

Step 8: Once the PI has signed the package, click 'Submit' this package. Select 'University of Denver (DU) IRB, Denver, CO' in the "Search for Organization" drop down menu (this will be your default location and should be highlighted already).

Step 9: To review what has been sent, click **PROJECT OVERVIEW**. The submission will be under 'Pending Review' status until a decision by the board has been made. Once a decision letter is formulated, an email will be sent to everyone who has full access and the letter and any supporting documents can be printed.

Keep in mind that once you click "Submit" your study is now locked and you are not allowed to attach any other documents or make revisions. Take the time to be sure all documents are attached, documents have been carefully proof-read and in the final version prior to submitting. Any incomplete submissions will not be reviewed by the IRB and will be returned for corrections.

The submission of an amendment of an open study requires the creation of subsequent package in a project.

Step 1: Login to IRBNet; www.irbnet.org. this will take you to the **MY PROJECTS** page.

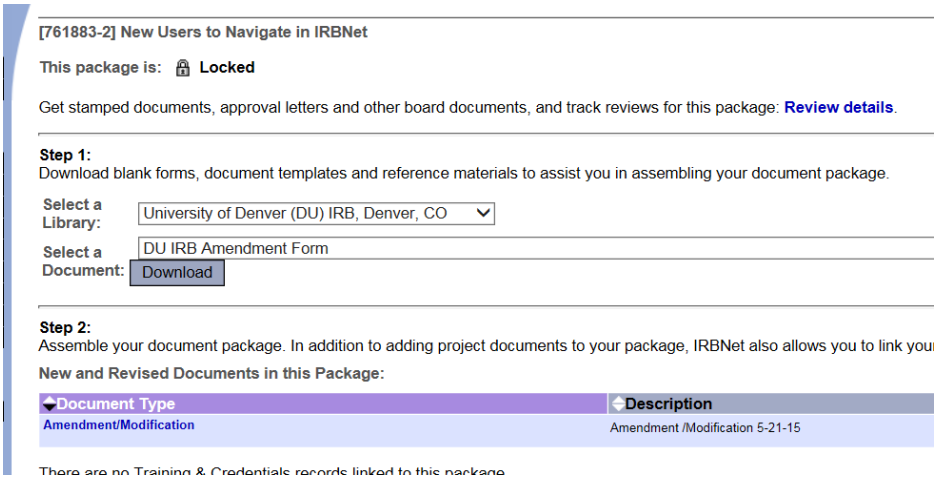
Step 2: Click on the Title of the project that you would like to amend/modify. Then click on the **PROJECT HISTORY**

Step 3: Click on the **CREATE NEW PACKAGE** button and then the **NEW DOCUMENT PACKAGE**

A **NEW DOCUMENT PACKAGE** will appear as a "**Work in Progress**". Click on the New Document Package title and you will be brought to the **DESIGNER** screen where you can add your documents for this package.

Step 4: You will now be on the **DESIGNER** page.

This is where you can access the library of forms as well as any documents form previous packages you have submitted.


[761883-2] New Users to Navigate in IRBNet
This package is: Locked
Get stamped documents, approval letters and other board documents, and track reviews for this package: Review details.
Step 1:
Download blank forms, document templates and reference materials to assist you in assembling your document package.
Select a Library:
University of Denver (DU) IRB, Denver, CO
Select a Document:
DU IRB Amendment Form
Download
Step 2:
Assemble your document package. In addition to adding project documents to your package, IRBNet also allows you to link you
New and Revised Documents in this Package:
Document Type
Description
Amendment/Modification
Amendment /Modification 5-21-15
There are no Training & Credentials records linked to this package

From the DU IRB Library (Step 1: - top of screen), Select and download both '**Checklist – Amendment/Modifications**' and '**Amendment/Modification Application**' from the 'Select A Document' drop down box. From here, chose File>Save As to save the amendment document to your computer, complete the Application Form, save to your hard drive and use the checklist as a reference guide.

If the amendment changes any of the data included in the previously approved On-Line Document (DU IRB Application), (i.e., personnel, study locations, contact information) then this form will need to be updated as a part of your amendment submission.

Attach supporting documents for your amendment package by clicking on the '**Add New Document**' button and browsing your computer:

In the Document type drop-down box, pick the best match for the document you are uploading. If it is the application, choose the "Application Form" choice. If the type of document you are submitting is not in the list then chose "Other" and enter the type of document in the Description field. Click the 'Browse' button and find the document on your hard drive. Once you find the document click the 'Attach' button to upload the document.

Repeat the steps to upload until all document s have been uploaded to your package.

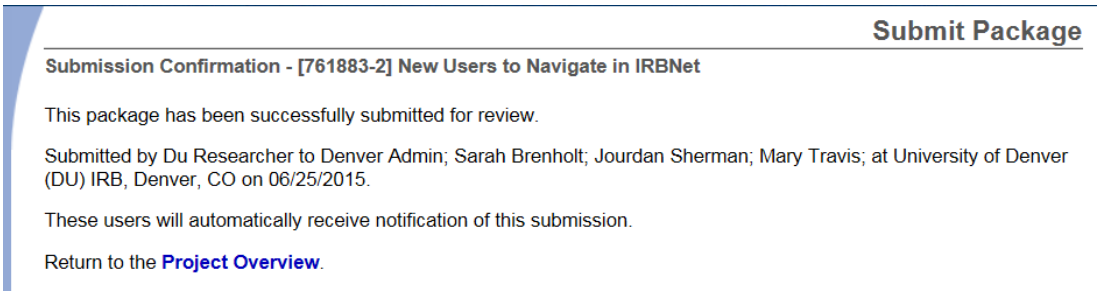
Step 5: When all documents are uploaded the PI needs to sign the package electronically. If you are a student, send an email (Send Project Mail) to your faculty advisor and have then **SIGN THIS PACKAGE**.

Step 6: To sign a package, click **SIGN THIS PACKAGE**. The Principal Investigator MUST sign the package before it is submitted Select your appropriate role form the dropdown box and click 'Sign'.

Step 7: Once the package has been signed, click **SUBMIT THIS PACKAGE** Select "DU IRB, Denver, CO" in the "Search for Organization" drop down menu (This will be your default location and should be highlighted already).

Then click the 'Continue' button. In the Submission type drop-down menu, select '**Amendment/Modification**' and click 'Submit'.

Once you hit the 'Submit' button, you will be given a confirmation showing the time your submission occurred.


Submit Package
Submission Confirmation - [761883-2] New Users to Navigate in IRBNet
This package has been successfully submitted for review.
Submitted by Du Researcher to Denver Admin; Sarah Brenholt; Jourdan Sherman; Mary Travis; at University of Denver (DU) IRB, Denver, CO on 06/25/2015.
These users will automatically receive notification of this submission.
Return to the Project Overview.

Step 8: To review what has been sent, click **PROJECT OVERVIEW**. The submission will be under 'Pending review' status until a decision has been made. Once a decision letter is formulated, an email will be sent to everyone who has full access and the letter and any supporting documents can be printed.

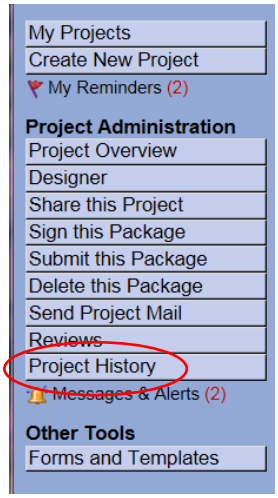
Keep in mind that once you click 'Submit' your study is now locked and you can no longer make any other changes to this package. Take the time to be sure all documents are attached and in the final version prior to submitting. Any incomplete submissions will not be reviewed by the IRB and will be returned for corrections.

VI. INSTRUCTIONS FOR SUBMITTING A STUDY CLOSURE

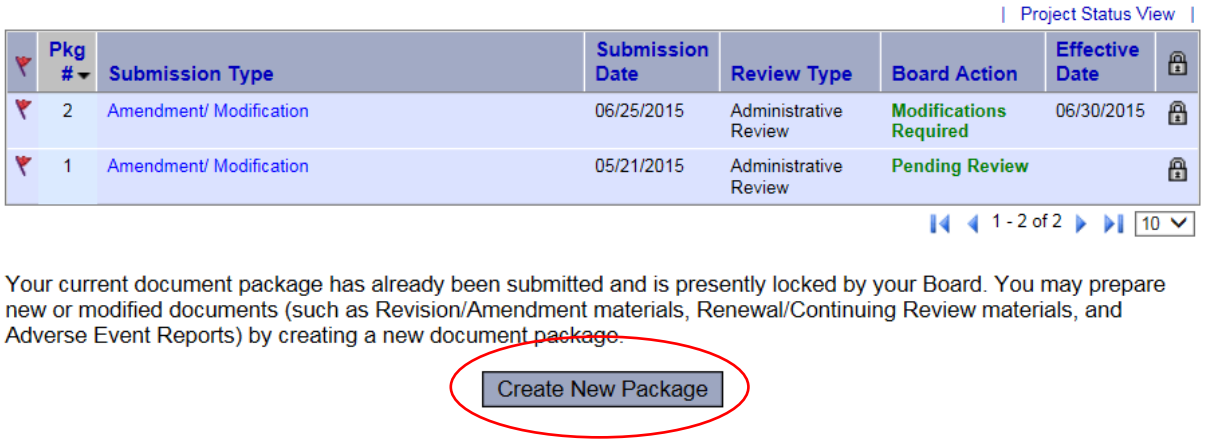
***The submission of a study closure of an open study requires the creation of a subsequent package in a project*.**

Step 1: Login to IRBNet: www.irbnet.org . This will take you to the **MY PROJECTS** page.

Step 2: Click on the Title of the project that you would like to close. Then click on the **PROJECT HISTORY**



Step 3: Click on the **CREATE NEW PACKAGE** button


| Project Status View |
Pkg # | Submission Type | Submission Date | Review Type | Board Action | Effective Date
2 | Amendment/ Modification | 06/25/2015 | Administrative Review | Modifications Required | 06/30/2015
1 | Amendment/ Modification | 05/21/2015 | Administrative Review | Pending Review |
1 - 2 of 2
10
Your current document package has already been submitted and is presently locked by your Board. You may prepare new or modified documents (such as Revision/Amendment materials, Renewal/Continuing Review materials, and Adverse Event Reports) by creating a new document package.
Create New Package

A NEW DOCUMENT PACKAGE will appear as a 'Work in Progress'. Click on the New Document Package title and you will be brought to the DESIGNER screen where you can add your documents for this package.

Step 4: You will now be on the **DESIGNER** screen where you can add your documents for this package.

From the DU IRB Library (Step 1: - top of screen), Select and download 'Final Report Application' from the '**Select A Document**' drop down box. From here, choose File>Save As to save document to your computer, complete the Final Report Application and save to your hard drive.

Step 5: Attach supporting documentation for your closure of the study. In the 'Document Type' box, pick the Closure/Final Report document type in the drop-down box. If the type of document you are submitting is not in the list then choose 'Other' and enter the type of document in the Description field. Click the 'Browse' button and find the document on your hard drive. Once you find the document, click the 'Attach' button to upload the document.

Repeat the steps to upload until all documents have been uploaded to your package

Step 6: When all required documents are uploaded to the package, the PI needs to **SIGN THIS PACKAGE** electronically. In order to sign a package, select your appropriate role from the drop-down box and click 'Sign'.

If a submission is submitted without the PI signature, or if you are a student researcher without a Faculty Advisor's signature, the submission will not be accepted as complete.

Step 7: Once the package has been signed, click **SUBMIT THIS PACKAGE**. Select 'DU IRB, Denver, CO' in the "Search for Organization" drop-down menu (this will be your default location and should be highlighted already).

Then click the 'Continue' button. In the Submission Type drop-down menu, select '**Closure/Final Report'** and click 'Submit'.

Once you hit the 'Submit' button, you will be given a confirmation showing the time your submission occurred.

Step 8: To review what has been sent, click **PROJECT OVERVIEW**. The submission will be under 'Pending Review' status until an acknowledgement is granted. Once a decisions letter is formulated, an email will be sent to everyone who has full access and the letter and any supporting documents can be printed.

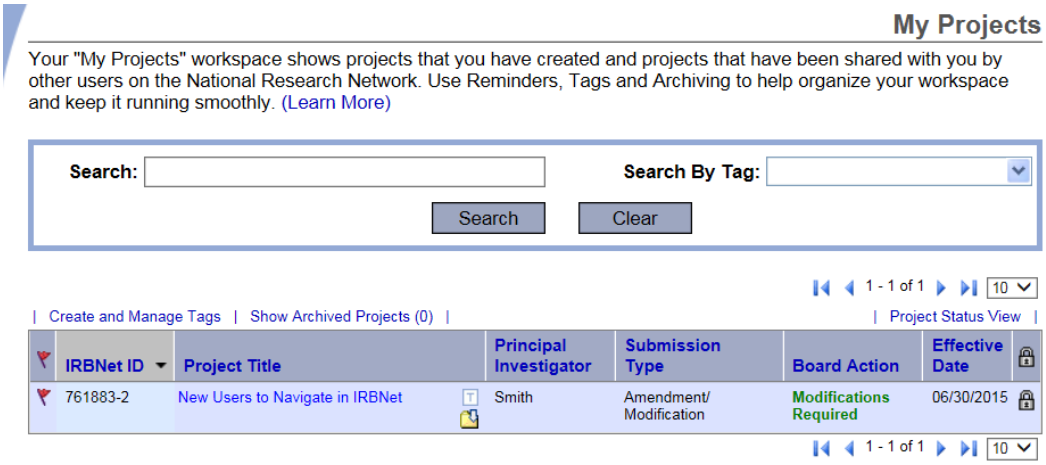
Keep in mind that once you click 'Submit' your study is now locked and no other changes can be made to this package. Take the time to be sure all documents are attached and in the final version prior to submitting. Any incomplete submissions will not be reviewed by the IRB and will be returned for corrections.

VII. INSTRUCTIONS FOR SUBMITTING ADVERSE EVENTS, PROTOCOL DEVIATIONS AND UNANTICIPATED PROBLEMS

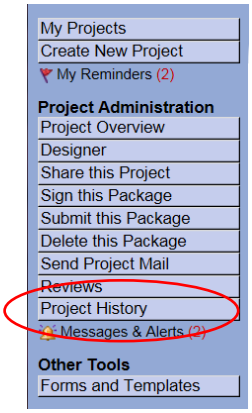
The Submission of an Adverse Event, Protocol Deviation or Unanticipated Problem will require the creation of a subsequent package in a project.

If you are unsure whether to submit as an adverse event or a reportable event, contact the IRB Office at 303-871-4050 for assistance.

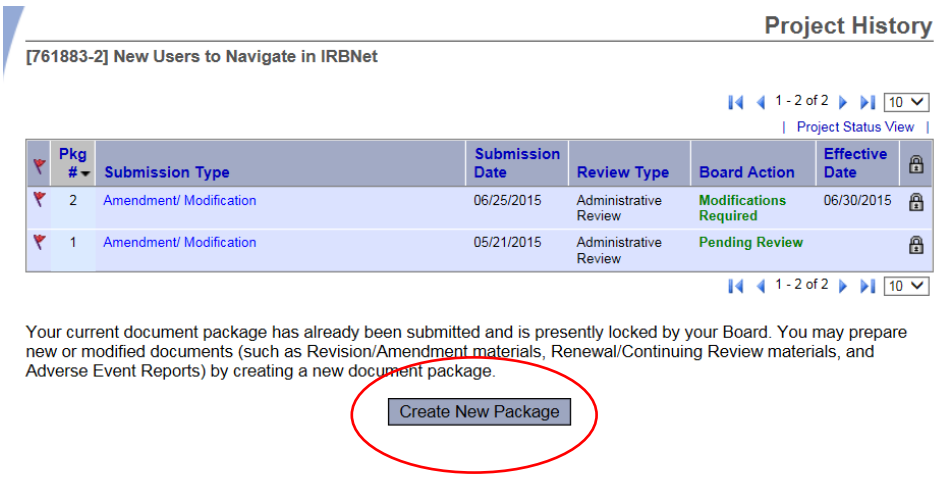
Step 1: Login to IRBNet: www.irbnet.org. This will take you to the **MY PROJECTS** page


My Projects
Your "My Projects" workspace shows projects that you have created and projects that have been shared with you by other users on the National Research Network. Use Reminders, Tags and Archiving to help organize your workspace and keep it running smoothly. (Learn More)
Search:
Search By Tag:
Search
Clear
1 - 1 of 1
10
Create and Manage Tags
Show Archived Projects (0)
Project Status View
IRBNet ID
Project Title
Principal Investigator
Submission Type
Board Action
Effective Date
761883-2
New Users to Navigate in IRBNet
Smith
Amendment/ Modification
Modifications Required
06/30/2015
1 - 1 of 1
10

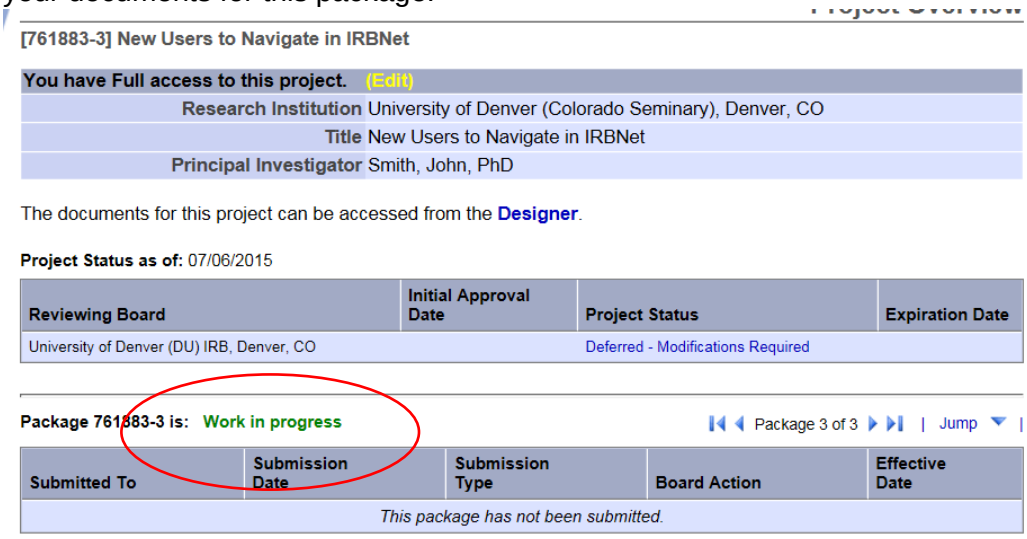
Step 2: Click on the Title of the project of which you are reporting. Then click on **PROJECT HISTORY** button



Step 3: Click on the **CREATE NEW PACKAGE** button

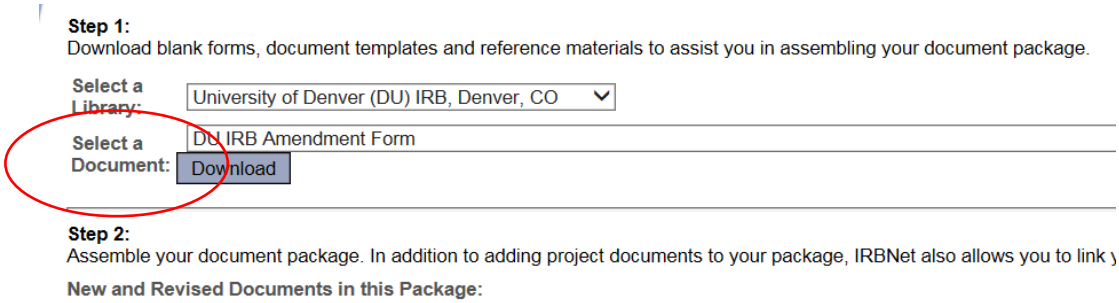


A **NEW DOCUMENT PACKAGE** will appear as a '**Work in Progress**'. Click on the New Document Package title and you will be brought to the **DESIGNER** screen where you can add your documents for this package.


[761883-3] New Users to Navigate in IRBNet
You have Full access to this project. (Edit)
Research Institution University of Denver (Colorado Seminary), Denver, CO
Title New Users to Navigate in IRBNet
Principal Investigator Smith, John, PhD
The documents for this project can be accessed from the Designer.
Project Status as of: 07/06/2015
Reviewing Board
Initial Approval Date
Project Status
Expiration Date
University of Denver (DU) IRB, Denver, CO
Deferred - Modifications Required
Package 761883-3 is: Work in progress
Package 3 of 3
Jump
Submitted To
Submission Date
Submission Type
Board Action
Effective Date
This package has not been submitted.

Step 4: You will now be on the **DESIGNER** screen where you can add your document for this package.

From the DU IRB Library (Step 1 – top of screen), Select and download the appropriate form for your submission type from the '**Select A Document**' drop down box. From here, choose File>Save As to save the document to your computer, complete the appropriate form(s) and save to your hard drive.


Step 1:
Download blank forms, document templates and reference materials to assist you in assembling your document package.
Select a Library:
University of Denver (DU) IRB, Denver, CO
Select a Document:
DU IRB Amendment Form
Download
Step 2:
Assemble your document package. In addition to adding project documents to your package, IRBNet also allows you to link
New and Revised Documents in this Package:

Add supporting documentation to your submission as appropriate.

Attach supporting documents for your package by clicking on the '**Add New Document**' button and browsing your computer:

Label your documents appropriately using the drop down list on the 'Attach Document' screen.

Step 5: When all required documents are uploaded to the package, the PI needs to **SIGN THIS PACKAGE** electronically. In order to sign a package, select your appropriate role from the dropdown box and click 'Sign'.

Note: If a submission is submitted without the PI signature, or without a Faculty Sponsor signature, the submission will not be accepted for review.

Step 6: Once the PI has signed the package, click **SUBMIT THIS PACKAGE**. Select 'DU IRB, Denver CO' in the "Search for Organization" drop down menu (This will be your default location and should be highlighted already).

Then click on the 'Continue' button.

In the Submission Type drop-down menu, select the appropriate submission type, either 'Adverse Event' or 'Protocol Deviation' and click 'Submit'.

Once you hit the 'Submit' button, you will be given a confirmation showing the time your submission occurred.

To review what has been sent, click **PROJECT OVERVIEW**. The submission will be under 'Pending Review' status until an acknowledgement is granted or an action has been taken. Once decision letter is formulated, an email will be sent to everyone who has full access and the letter and any supporting documents can be printed.

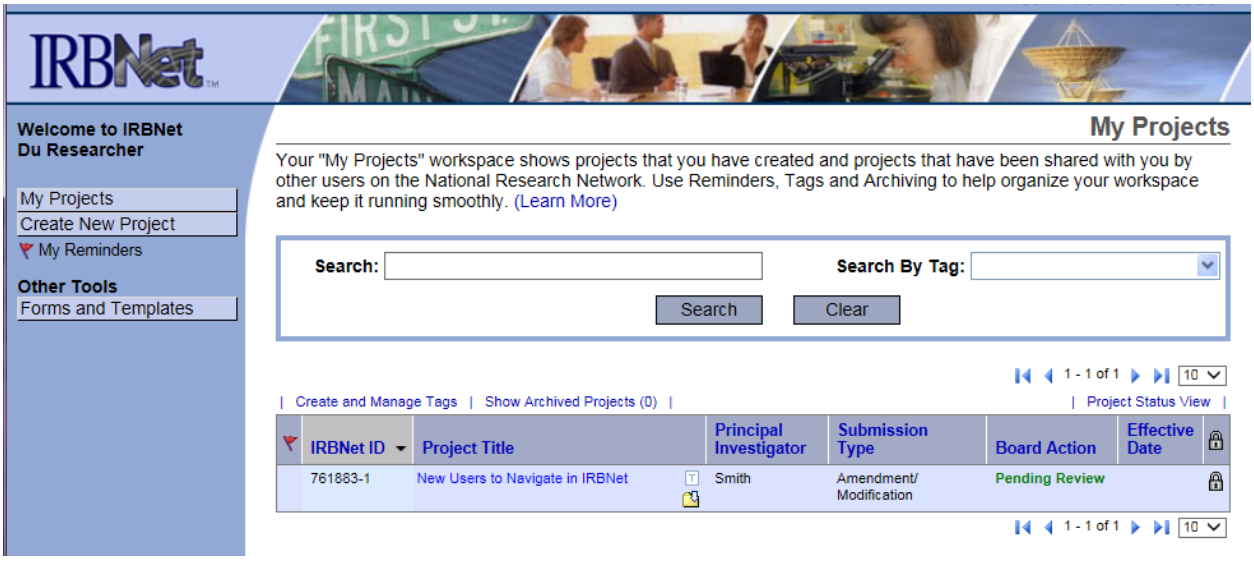
Keep in mind that once you click 'Submit' your study is now locked and no other changes can be made to this package. Take the time to be sure all documents are attached and in the final version prior to submitting. Any incomplete submission will not be reviewed by the IRB and will be returned for corrections.

VIII. INSTRUCTIONS FOR SUBMITTING REVISIONS REQUESTED BY THE BOARD

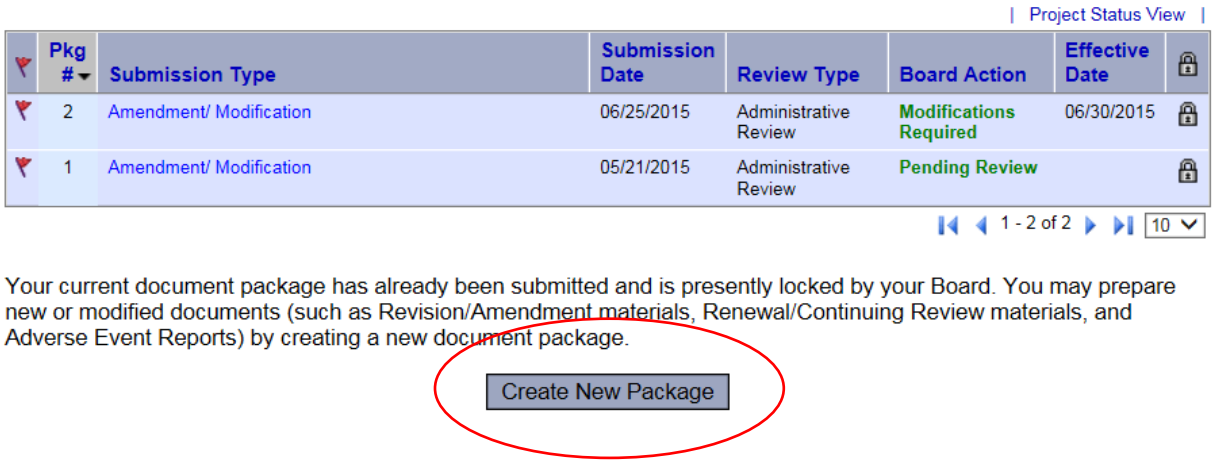
If you have submitted a package and the full board has determined that "Modifications are Required" then you need to submit a 'Revision'.

Step 1: Login to IRBNet: www.irbnet.org. This will take you to the **MY PROJECTS** page.

Step 2: Click on the Title of the project that your submitting revisions to and click on the **PROJECT HISTORY**



Step 3: Click on the **CREATE NEW PACKAGE** button and then the **NEW DOCUMENT PACKAGE**



A **NEW DOCUMENT PACKAGE** will appear as a "Work in Progress".

Project Status as of: 06/30/2015

Reviewing Board	Initial Approval Date	Project Status	Expiration Date
University of Denver (DU) IRB, Denver, CO		Deferred - Modifications Required	

Package 761883-3 is: Work in progress Package 3 of 3 | Jump |

Submitted To	Submission Date	Submission Type	Board Action	Effective Date
This package has not been submitted.				

Click on the '**Work in progress**' title and you will be brought to the **DESIGNER** screen where you can add your documents for this package.

Step 4: You will now be on the **DESIGNER** screen where you can add your documents for this package.

Step 5: To revise an uploaded document (.doc,.xls,.pdf, etc.) from a previous package:

First download the document by clicking on its **Document Type** or the paper icon

If you will be revising a consent document, be careful to ensure that the document you will downloading and revising is identical to the most current, IRB-approved version that sits in the Board Documents Section.

Make necessary changes and save the revised document to your computer. Be sure to include BOTH a **tracked** changes version of your document showing what is changing as well as a **clean copy** for a new approval stamp.

You can find instructions on how to use 'tracked changes' under the Forms and Templates tab under 'Other Tools'. Look for the document entitled '**GUIDANCE – How to Use Track Changes in Documents**'.

Click on the pencil icon for that document on the **Designer** page.

Browse your computer and select your revised version of the document to upload, make changes to the Document Type and Description as appropriate, and click the Update button.

If you need to add a new document, then click on the '**Add New Document**' button.

To revise the **DU IRB Application Form** from a previous package for committee review:

Click on the pencil icon for the **IRB Application Form**.

This will open up the **DU IRB Application Form** (IRBNet Document Wizard screen)

Use the Jump To: feature in the upper right corner of the IRBNet Document Wizard page to **Jump** to the section that you are revising

Click on the 'Save and Exit' button when you have made all of your changes

The document will move to the 'New and Revised Documents in this Package' section on the **DESIGNER** page.

Step 5: Click **SIGN THIS PACKAGE**. The PI signature is required for all submissions. If you are a student researcher, your Faculty Advisor must also sign the package.

Step 6: Click on **SUBMIT THIS PACKAGE**; click on "DU IRB, Denver, CO" in the 'Select Organization' box. Then click on 'Continue'

In the Submission Type drop-down menu, select '**Revisions**' and click 'Submit'.

In the "Your Comments" section, specify what the revision is for –(i.e. , response to new study submission, amendment submission, continuing review submission, etc.). This will assist the board in processing your revision in a more efficient and timely manner.

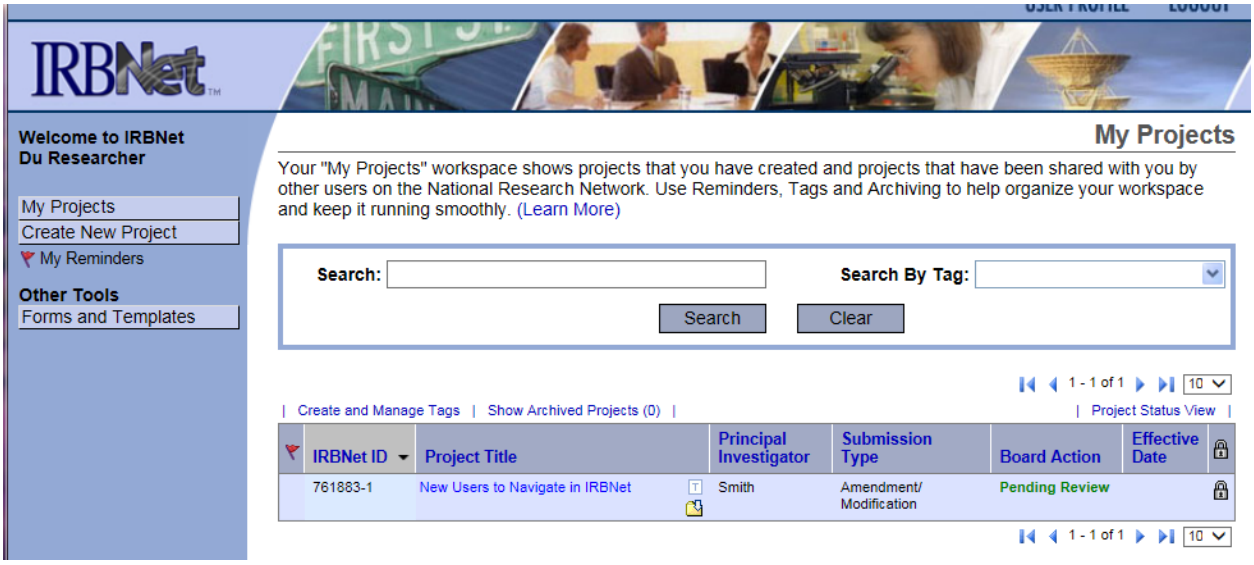
To review what has been sent, click **PROJECT OVERVIEW**. The submission will be under 'Pending Review' status until a decision has been made.

Take the time to be sure all documents are attached and in the final version prior to submitting Incomplete submissions will be unlocked by the IRB Office and the IRB review will be delayed. An email will be sent to the PI identifying the missing documents or items in the package.

INSTRUCTIONS FOR SUBMITTING REVISIONS REQUESTED BY THE DU IRB ADMINISTRATIVE OFFICE (INCOMPLETE SUBMISSIONS)

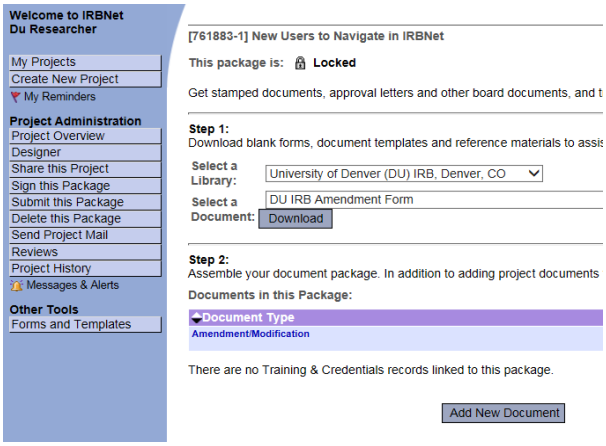
During the IRB administrative preliminary review, each submission will be evaluated for completeness. If a submission is incomplete the PI will receive an email that lists what is missing or what changes need to be made to the document.

Step 1: Login to IRBNet: www.irbnet.org. This will take you to the **MY PROJECTS** page



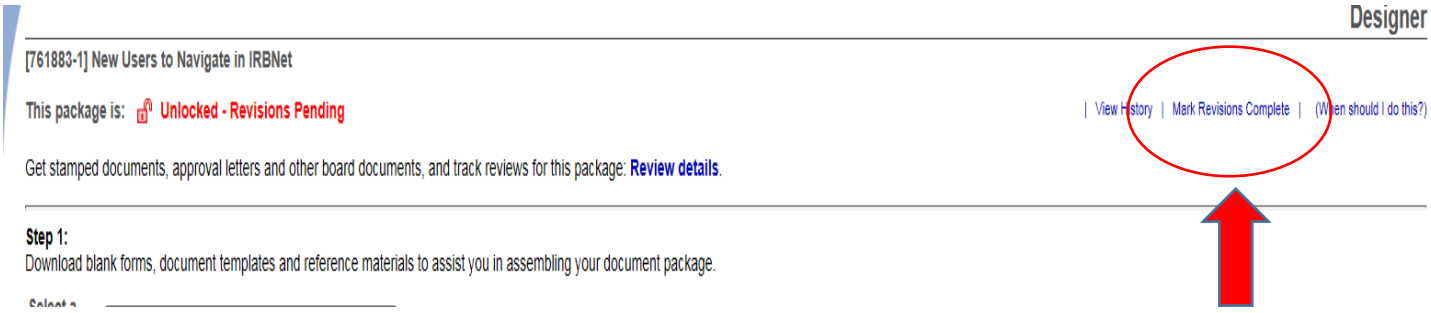
Step 2: Click on the Title of the project of which you are submitting missing and/or corrected documents.

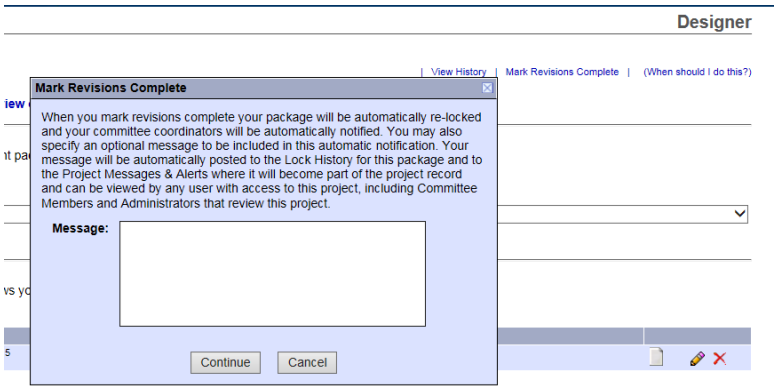
Step 3: Click the **DESIGNER.**



From here, you can upload revised documents for your study by clicking on '**Add New Document**'. Browse for your revised documents and any other relevant information from your computer and assign the proper Document Type from the drop-down menu. Click 'Attach'.

Step 4: To relock the package, Click on 'Mark Revisions Complete'.


Designer
[761883-1] New Users to Navigate in IRBNet
This package is: Unlocked - Revisions Pending
| View History | Mark Revisions Complete | (When should I do this?)
Get stamped documents, approval letters and other board documents, and track reviews for this package: Review details.
Step 1:
Download blank forms, document templates and reference materials to assist you in assembling your document package.


Designer
| View History | Mark Revisions Complete | (When should I do this?)
Mark Revisions Complete
When you mark revisions complete your package will be automatically re-locked and your committee coordinators will be automatically notified. You may also specify an optional message to be included in this automatic notification. Your message will be automatically posted to the Lock History for this package and to the Project Messages & Alerts where it will become part of the project record and can be viewed by any user with access to this project, including Committee Members and Administrators that review this project.
Message:
Continue
Cancel

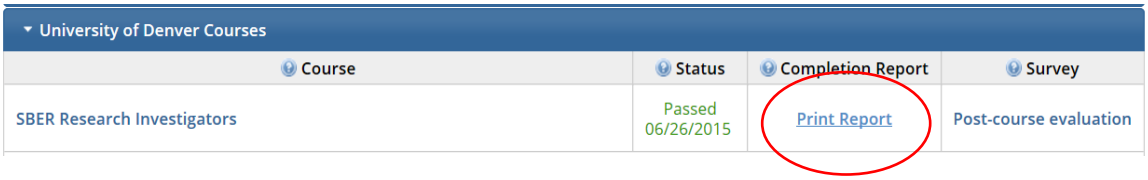
Step 5: Check the status of your review. Go to **Review Details**

Review Details include Agenda Date, Review Type, Status, Effective and Expiration Dates, and Board Documents

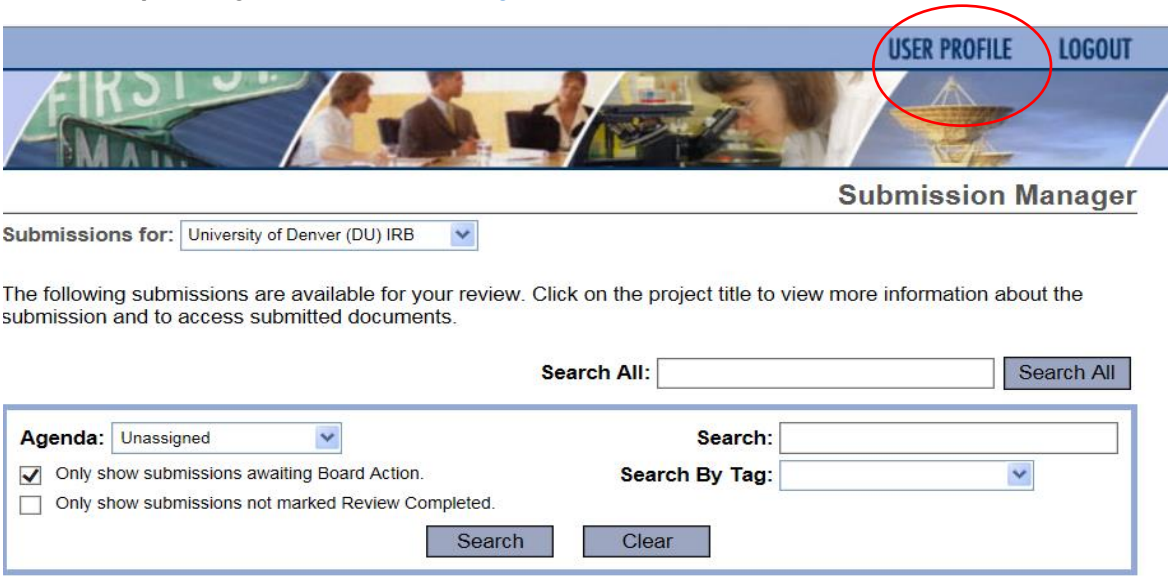
INSTRUCTIONS FOR ATTACHING YOUR CITI TRAINING

www.citiprogram.org

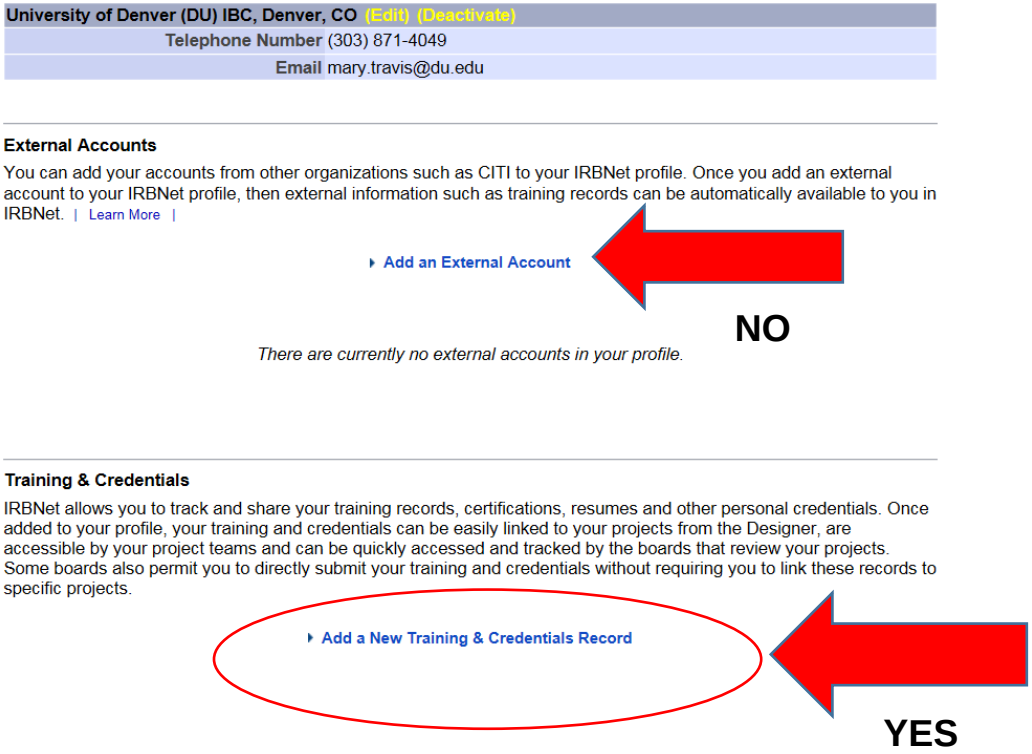
Step 1: After you have successfully completed the required modules, click on 'Print Report', Save as "CITI Training Certificate" on your computer.



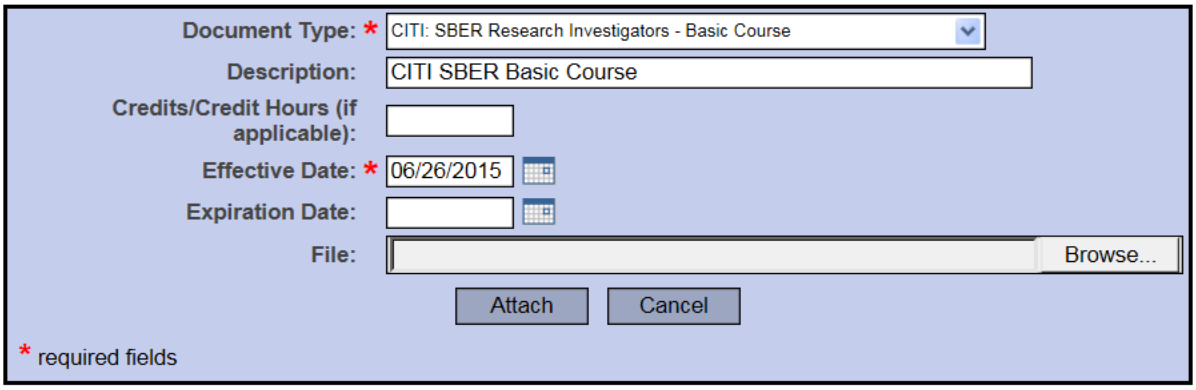
Step 2: Log onto www.IRBNet.org and click on User Profile


USER PROFILE
LOGOUT
Submission Manager
Submissions for: University of Denver (DU) IRB
The following submissions are available for your review. Click on the project title to view more information about the submission and to access submitted documents.
Search All:
Search All
Agenda: Unassigned
Search:
Only show submissions awaiting Board Action.
Search By Tag:
Only show submissions not marked Review Completed.
Search
Clear

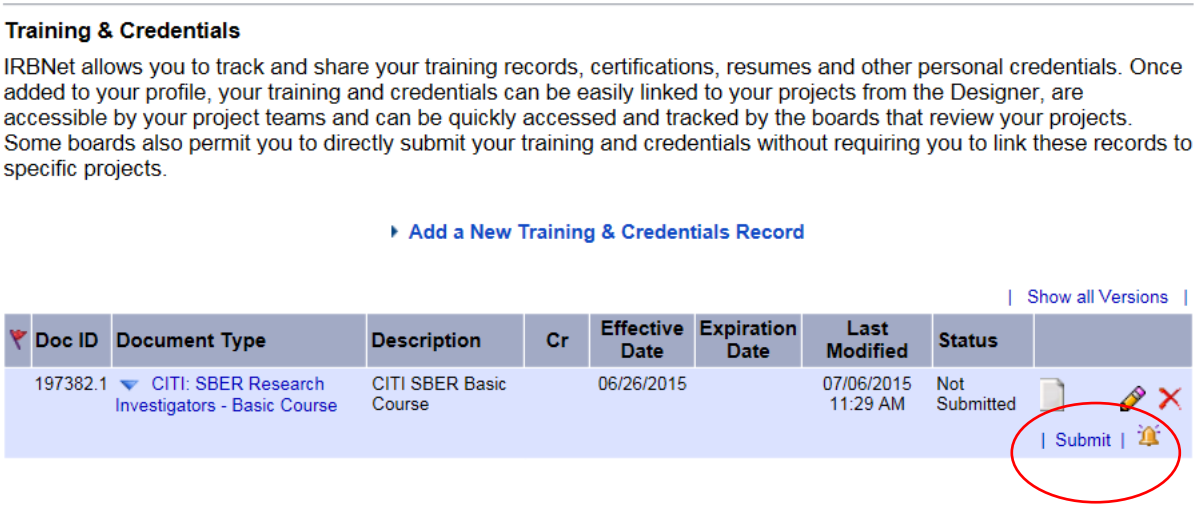
Step 3: Scroll down to "Training and Credentials" and click on "add a new training and credentials record". **DO NOT click on "Add an External Account".**


University of Denver (DU) IBC, Denver, CO (Edit) (Deactivate)
Telephone Number (303) 871-4049
Email mary.travis@du.edu
External Accounts
You can add your accounts from other organizations such as CITI to your IRBNet profile. Once you add an external account to your IRBNet profile, then external information such as training records can be automatically available to you in IRBNet. | Learn More |
Add an External Account
NO
There are currently no external accounts in your profile.
Training & Credentials
IRBNet allows you to track and share your training records, certifications, resumes and other personal credentials. Once added to your profile, your training and credentials can be easily linked to your projects from the Designer, are accessible by your project teams and can be quickly accessed and tracked by the boards that review your projects. Some boards also permit you to directly submit your training and credentials without requiring you to link these records to specific projects.
Add a New Training & Credentials Record
YES

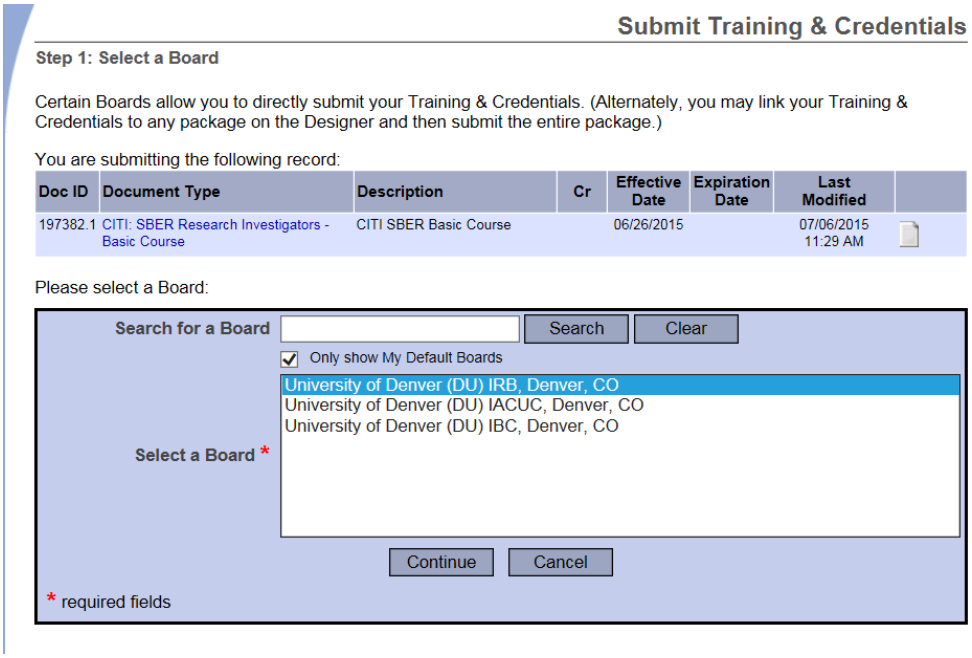
Step 4: Select the document type, enter a description and put in the date you completed the course. Browse and upload the certificate from your computer and click 'Attach'.



Step 5: Click on 'Submit'


Training & Credentials
IRBNet allows you to track and share your training records, certifications, resumes and other personal credentials. Once added to your profile, your training and credentials can be easily linked to your projects from the Designer, are accessible by your project teams and can be quickly accessed and tracked by the boards that review your projects. Some boards also permit you to directly submit your training and credentials without requiring you to link these records to specific projects.
Add a New Training & Credentials Record
| Show all Versions |
Doc ID
Document Type
Description
Cr
Effective Date
Expiration Date
Last Modified
Status
197382.1
CITI: SBER Research Investigators - Basic Course
CITI SBER Basic Course
06/26/2015
07/06/2015 11:29 AM
Not Submitted
| Submit |

Step 6: Select the correct board "University of Denver (DU) IRB, Denver. CO" and click "Continue". A confirmation will appear. As the final step, click 'Submit'.


Submit Training & Credentials
Step 1: Select a Board
Certain Boards allow you to directly submit your Training & Credentials. (Alternately, you may link your Training & Credentials to any package on the Designer and then submit the entire package.)
You are submitting the following record:
Doc ID
Document Type
Description
Cr
Effective Date
Expiration Date
Last Modified
197382.1
CITI: SBER Research Investigators - Basic Course
CITI SBER Basic Course
06/26/2015
07/06/2015 11:29 AM
Please select a Board:
Search for a Board
Search
Clear
Only show My Default Boards
University of Denver (DU) IRB, Denver, CO
University of Denver (DU) IACUC, Denver, CO
University of Denver (DU) IBC, Denver, CO
Select a Board *
Continue
Cancel
* required fields

Step 2: Confirm and Submit

Doc ID	Document Type	Description	Cr	Effective Date	Expiration Date	Last Modified	
197382.1	CITI: SBER Research Investigators - Basic Course	CITI SBER Basic Course		06/26/2015		07/06/2015 11:29 AM	

You are submitting this record to the following Board:

University of Denver (DU) IRB, Denver, CO

You may also send an optional message to the Board along with this submission:

Subject: New Training & Credentials Submission

Your Message:

Submit Cancel

Training & Credentials

IRBNet allows you to track and share your training records, certifications, resumes and other personal credentials. Once added to your profile, your training and credentials can be easily linked to your projects from the Designer, are accessible by your project teams and can be quickly accessed and tracked by the boards that review your projects. Some boards also permit you to directly submit your training and credentials without requiring you to link these records to specific projects.

▸ Add a New Training & Credentials Record

| Show all Versions |

Doc ID	Document Type	Description	Cr	Effective Date	Expiration Date	Last Modified	Status	
197382.1	CITI: SBER Research Investigators - Basic Course	CITI SBER Basic Course		06/26/2015		07/06/2015 11:29 AM	Pending Review		Submit

FREQUENTLY ASKED QUESTIONS (FAQs)

What studies do I have access to?

The **MY PROJECTS** screen can be found by clicking on 'My Projects' on the left side of your screen. This will show you the list of studies to which you have access – those you have created and those which have been shared with you. Studies which have not been submitted are labels '**Work in Progress**' in the Status column. Studies which have been submitted but not reviewed by the IRB are labeled 'Pending Review'.

Clicking on the title of any project will take you to the **PROJECT OVERVIEW** page for the selected project which contains project details.

What if I submit an incomplete package?

If you have forgotten to add a necessary document or need to make a quick change to a recently submitted project package, contact the DU IRB Office at 303-871-4050.

My Faculty Advisor says they signed up in IRBNet but I cannot share the project with them?

Anyone can trigger an Activation email by logging into their account on IRBNet and clicking the link provided. If they are not finding the Activation email in their inbox, please have them check their Spam folder. Once they opent he Activation email, clicking the link provided will activate their account and allow them to log in on IRBNet.

How do I know if my Faculty Advisor has signed the package?

To know when your Faculty Advisor has singe doff on a package, asken them to click the send mail button when they have signed. This wills end an automatically generate email form them letting your know they have signed. If they do not do this, you can log-in and review if they have signed by clicking on the SIGN THIS PACKAGE tab on the left of your screen. This will bring you to a list of who has signed this study and when it was completed.

What level of access should your Faculty Advisor have?

It is up to you as the Principal Investigator to decide what kind of access shared individuals should have. It bears repeating: those with full access will receive e-mails when the IRB posts an action or decision.

What does my electronic signature mean?

The DU IRB requires that the Principal Investigator sign each submission. If you are a student investigator, your Faculty Advisor must also sign each submission. Having a Faculty Advisor sign each submission indicates that they have reviewed and approve your submission. As the Principal Investigator, your electronic signature that is associated with a given project means that eh research described in the application and supporting materials will be conducted in full compliance with DU IRB's policies and Federal regulations governing human subjects research.

Locked vs. Unlocked Status

Once a study is submitted to the IRB, it will be LOCKED.

Package can only be unlocked by the DU IRB Administrative staff. This can be done if you let us know that you've made an error in something that you just submitted, or if we let you know that we see something that is missing or needs to be fixed. When you need to respond to a DU IRB review, or if you want to submit an amendment, or continuing review, you will **CREATE NEW PACKAGE** for the project by adding documents in the **DESIGNER** for that project.

I have submitted a Continuing Review application, why am I still receiving an IRBNet 30-day Project Expiration Reminder?

Reminders are automatically generated until the submission has been approved by the IRB. IF you can see the Continuing Review submission in **PROJECT HISTORY** the IRB staff has access to it. **PROJECT HISTORY** will show the Status as Pending Review until a determination letter is issued by the IRB.

EXPLANATION OF IRBNet TERMS

Project	A Project is an online version of the research protocol being submitted to the DU IRB
Project Package	A package is a submission containing any number of documents that are required by the IRB to conduct their review of a research Project (i.e. initial project, amendment, continuing review, etc.)
Submission	IRBNet uses the term Submission to denote a Project Package that has been submitted for official review by the IRB
Principal Investigator	IRBNet uses the term Principal Investigator (PI) to designate the person with overall responsibility for studies submitted to the DU-IRB. All studies must have a PI and all submission must include a PI signature.
Amendment/Modification	Amendment/Modifications are changes that the researcher wishes to make after a study is approved by the IRB. The researcher must submit an amendment/modification package for IRB approval.
Revision	A revision is a change (or changes) required by the IRB before a project or package can be approved. The researcher creates a new Project Package in IRBNet to address any required revisions.
My Projects	Lists all projects you have created. You enter the study by selecting it from the list.
Create New Project	Allows you to enter a New Study for submission. The Initial Project package will include the appropriate applications, the full research narrative, any surveys or instruments, consent forms and any other required documents.
Project Overview	Summarizes the selected project, displays the status and documents. Allows you to submit the package for review, and share with other IRBNet users.
Designer	This page contains two steps. Step 1 lists the document library where you can find forms to guide you or to fill out (i.e., checklists, applications). Step 2 allows you to upload your documents to a package. This is called “Assemble our document package”. This means you are putting your proposal together.
Share this Project	Allows you to share your project with other registered IRBNet researchers.
Sign this Package	All packages must include the Principal Investigator signature prior to submission. For student investigators, all packages must include their Faculty Advisor’s signature prior to submission.
Submit this Package	After the PI signs the package, you will need to submit the package to the DU IRB. Once you submit a package, it remains in the system permanently.
Delete this Package	IF you want to remove the package completely, this cannot be undone.
Send Project Mail	Allows you to send an e-mail between members of the project team.
Project History	Lists the Actions related to this project
Board Documents	These are decision documents and stamped documents issued by the board in response to your package submission.

HOW TO LABEL YOUR SUBMISSIONS

When submitting the following items, use the appropriate **SUBMISSION TYPE** within IRBNet:

ITEM	SUBMISSION TYPE
Exempt Initial Submission	New Project
Expedited/Convened IRB Initial Submission	New Project
Continuing Review	Continuing Review/Progress Report
Amendment	Amendment/Modification
Consent Revision	Amendment/Modification
Protocol Revision	Amendment /Modification
Study Closure	Closure/Final Report
Response to Approval with Modifications from the IRB	Revision
Response to Additional Materials Request or follow-up from the IRB	Revision
Correspondence	Other
Local SAEs	Reportable Event/(Non AE)
Protocol Deviation	Reportable Event/(Non AE)
Unanticipated Problem	Reportable Event/(Non AE)
Compliance Concern	Reportable Event/(Non AE)
Information from Sponsor/Notification to the IRB	Amendment/Modification